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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/743,997 | 12/24/2003 | Yukio Nihei | 245553US0CONT | 9427 |
| 22850 | 7590 | 12/21/2005 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | WEDDINGTON, KEVIN E | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1614 | | |
| DATE MAILED: 12/21/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/743,997 | NIHEI ET AL. | |
| | Examiner | Art Unit | |
| | Kevin E. Weddington | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) 16-28 is/are withdrawn from consideration.
- 5) Claim(s) 29 is/are allowed.
- 6) Claim(s) 1-4,6-8,10 and 12-15 is/are rejected.
- 7) Claim(s) 5, 9 and 11 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Claims 1-29 are presented for examination.

Claim 1-15 and 29 are the elected invention.

Claims 16-28 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Applicants' response filed September 15, 2005 has been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph as set forth in the previous Office action dated May 20, 2005 at pages 2-5 is hereby withdrawn.

Allowable Subject Matter

Claim 29 is allowable.

Claim Objections

Claims 5, 9 and 11 are again objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-8, 10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pettit (5,561,122) or Cushman et al., "Synthesis and Evaluation of a Series of Benzylaniline Hydrochlorides as Potential Cytotoxic and Antimitotic Agents

Acting by Inhibition of Tubulin Polymerization", J. Med. Chem., 1993, Vol. 36, pp. 2817-2821 in view of Fex et al. (3,732,260), all of record, for reasons of record as set forth in the previous Office action dated May 20, 2005 at pages 5-7 as applied to claims 1-4, 6-8, 10 and 12-15.

Applicants' remarks regarding the prior art, Pettit or Cushman et al. in view of Fex et al., do not teach the tubulin polymerization inhibitory active substances having anti-tumor activity in combination with anti-inflammatory active substances having anti-tumor activity in a single composition are not persuasive since the instant rejection is based upon the well established principle of patent law that no invention resides in combining 2 or more ingredients of known character, where the results obtained are no more than the additive effects of the individual ingredients. It has not been demonstration on the record, by means of experimental data commensurate in scope with the claimed subject matter that applicants' combination produces any unobviousness or unexpected results. The mere arguments of applicants are insufficient to overcome the strong prima facie case of obviousness without the experimental data.

The rejection made under 35 USC 103 is adhered to.

Claims 1-4, 6-8, 10 and 12-15 are not allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1614

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Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
December 13, 2005